

From: [Chris Wozniak](#)
To: alan.mchughen@ucr.edu
Subject: Re: Fw: Quick one...
Date: Thursday, July 17, 2014 11:11:26 PM

Hey Alan,

I will need to check when I get back to the office but I think Sharlene's chapter was the only one to specifically mention stacks or pyramids. EPA is the only agency to regulate the merger of two previously approved traits whether through classical breeding or the re-transformation of a PIP plant with a second pesticidal trait. It is an artefact of FIFRA and pesticide regulation. APHIS and FDA ignore it! We ask for registration of breeding intermediates when making stacks / pyramids. Our SAP also suggested we do so. As new stacks / pyramids come in, registrants test all proteins simultaneously for acute toxicity so eventually this aspect will fade.

EPA issues a new label and registration when two previously individually registered traits are combined into one plant product. Same when two chemicals are merged. We assay for synergism with a target pest bioassay and anything greater than additive effect is sent back to a review of the mammalian toxicity (with multiple proteins). Never seen one yet though, even though Cry34/35 are synergistic.

Great to see you and glad we had some time for mojitos! Also glad your meetings went well. Did Tom make the trip?

Chris

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On 7/17/2014 9:48 PM, Wozniak, Chris wrote:

From: Alan McHughen alan.mchughen@ucr.edu
Sent: Thursday, July 17, 2014 6:30:10 PM
To: Wozniak, Chris
Subject: Quick one...

Hi Chris,

Do you recall if anyone talked about regulations with stacked traits in the book? I know the US doesn't regulate a new variety when two independent events are crossed to combine the new traits in one plant, but is that explicitly discussed anywhere?

I presume EPA would still have to approve the new pesticide regime if two individually approved Pips were crossed to combine them...?

Alan

